



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/649,396      | 08/27/2003  | Alexander G. Lastovich | P-5369B             | 6079             |

26253 7590 10/05/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL  
BECTON, DICKINSON AND COMPANY  
1 BECTON DRIVE, MC 110  
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

STIGELL, THEODORE J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3763

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NIF

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/649,396             | LASTOVICH ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Theodore J. Stigell    | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application.                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/17/04, 8/27/03</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

The Election of Species is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 16-19, 21, and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Min (5,618,295). Min discloses a microprotrusion array for the rotational delivery of a fluid substance into tissue, the array comprising at least one platen (50), the platen comprising a microprotrusion surface, and a platen edge (the edge of 50), wherein the surface is suitable for attaching a plurality of microprotrusions thereon, a plurality of microprotrusions (48) attached on the surface, wherein each microprotrusion comprises at least one scraping edge, at least one fluid substance retaining means, the means comprising intra-microprotrusion spacing, one or more recesses between the microprotrusions, and one or more areas devoid of microprotrusions (Figure 3B), wherein there is differing microprotrusion densities, wherein the platen edge has a thickness and is smooth, wherein the surface is planar or lenticular, the surface is non-uniform, wherein the microprotrusions range from 5 to 500 microns, wherein the platen is integral with a rotary device, and wherein Min discloses a method of delivering substance into the skin comprising positioning a housing and

Art Unit: 3763

mechanically rotating the microprotrusion array and using the housing to keep the skin taut and applying the substance after abrading.

Claims 1-4 and 7-24 rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (WO 02/032331). Sherman discloses a microprotrusion array for rotational delivery of a fluid substance into tissue, comprising at least one platen (240), the platen comprising a microprotrusion surface, and a platen edge (side of 240), wherein the surface suitable for attaching a plurality of microprotrusions thereon, a plurality of microprotrusions (52, 102, 12) attached in or on said microprotrusion surface of the platen, wherein each microprotrusion comprises at least one scraping edge, and at least one fluid substance retaining means, the means comprising intra-microprotrusion spacing, one or more recesses between microprotrusions, wherein the microprotrusions comprise areas of differing microprotrusion densities, wherein the platen edge has a thickness and is smooth, wherein the surface is planar or lenticular, wherein the surface is non-uniform, wherein the microprotrusions further comprise a base and a circumference, a tip, and a length from the tip to the base, wherein the surface comprises intersecting channels (Figure 24), wherein the microprotrusion length can vary in length from the edge to the center, wherein the lengths range from 5 to 500 microns, wherein the array comprises two or more platens (52, 102, 12) with protrusions arranged in rows offset from one another.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min (5,618,295) or Sherman (WO 02/032331). Min and Sherman disclose a microprotrusion array that includes all of the limitations as recited in claim 1, but fail to disclose a beveled or radiused platen edge. However, these parameters are deemed to be matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700